DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M2563N

April 27, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 28

Diane Pearson
Administrator
Cook County North Shore Hospital
503 West Fifth Street
Grand Marais, Minnesota 55604

Re: ID 1999350004

Dear Ms. Pearson:

We are writing to you because on April 1, 1999, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography performed at your facility.

Under a United States Federal law (the Mammography Quality Standards Act of 1992) (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 and Level 2 findings at your facility:

Level 1

1. Based on the documentation your site supplied during the inspection, it appears that interpreting physicians ([redacted] are not licensed by a State to practice medicine.

2. Based on the documentation your site supplied during the inspection, it appears that interpreting physicians ([redacted] do not meet the requirement of (a) being board-certified by any of the approved boards, or (b) having had two months of full-time training in interpretation of mammograms (equivalent to 280 hours). This may include time spent in residency if documented by the Residency program. Self-attestation is **not** acceptable.

Level 2

3. Based on the documentation your site supplied during the inspection, interpreting physicians ([redacted]) do not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a six-month period).

4. Based on the documentation your site supplied during the inspection, interpreting physicians ([redacted] do not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.

   • Note: If the physician meets item 2 via route (b) then they are exempt v from this item.

5. The measured darkroom fog density is equal to 0.3 at your site.

The specific problems noted above appeared on your MQSA Facility Inspection Reports which were issued to your facility following the close of the inspection. Problems identified as Level 1 indicate failures to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially

comply with, the MQSA, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

the specific steps you have taken to correct all of the violations noted in this letter; and

each step your facility is taking to prevent the recurrence of similar violations.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

Please submit your response to Tom Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

If you have more specific questions about mammography facility requirements or about the content of this letter please feel free to contact Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

James A. Rahto
Director
Minneapolis District

TWG/ccl

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